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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/179,188	10/27/1998	TOSHINARI SAKURAI	KAS-125	5396

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/17/98

Applicant(s)

Saturai et al

Examiner

Hodg

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/13/03 + 3/10/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 20-29 + 32-52 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 20-29 + 32-52 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) filed 1/13/03
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

The amendment of 1/13/03 amended claims 20 and 25-32.

The amendment of 3/10/03 canceled claims 30 and 31, amended claims 20, 25 and 29, and added new claims 33-52.

Claims examined on the merits are 20-29 and 32-52 which are all
5 claims in the application.

Documents have been lined through on form PTO-1449 of 1/13/03 were previously considered on form PTO-1449 of 12/14/01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10 ***Claim Rejections - 35 USC § 112***

Claims 20-29 and 32-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,
15 had possession of the claimed invention.

The specification fails to disclose carrying out steps separate from each other and in turn as required in the last two lines of claims 20, 25 and 32, and separate preparation of solutions and in turn as required in the last two lines of claims 26 and 27.

20 Applicants refer to page 9, lines 19-28, as providing support. However, this disclosure relates to describing an apparatus for recovery of nucleic acids, and not to describing methods as claimed.

The specification fails to disclose a method as required by claim 26 for recovering nucleic acids from a nucleic acid-bearing material.

25 Providing first, second and third solutions, and a solution containing an

alcohol and a salt, and carrying out only steps of separating material containing adsorbed nucleic acids, eluding the adsorbed nucleic acids and removing alcohol and salt contained in the eluted nucleic acids is not disclosed in the specification. The specification discloses only methods
5 of recovering nucleic acids from a nucleic acid-bearing material requiring six steps as set forth from page 6, line 5 from the bottom, to page 9, line 6.

Applicants urge that the steps of the claim are similar to basic steps of non-rejected claims such as claim 20. However, the steps of
10 claim 26 are not similar to the steps of claim 20. While removing alcohol and salt is disclosed, such removal is not disclosed in a method as required by claim 26.

The specification fails to describe a method of isolating a substance containing silicon oxide to which a nucleic acid is bound as
15 required by claims 27-29 and 32. There is no disclosure that the invention is to be a method of isolating a substance containing silicon oxide to which a nucleic acid is bound instead of a method of recovering nucleic acids from a nucleic acid-bearing material. Additionally, there is no description of performing such a method by only preparing first,
20 second and third solutions separately as required by claim 27, and by only providing a first solution and then carrying out two steps of transferring as in claim 32. As set forth above, the specification describes only methods requiring six steps for recovering nucleic acids from a nucleic acid-bearing material.

Contrary to applicants' argument, the specification nowhere recites or adequately supports an invention as claimed. Applicants have not pointed out the page and lines where support is provided. While claims 27 and 32 may not be limited to only the steps recited, the steps recited are the only steps used to perform the methods as claimed, and methods containing only the steps recited are not supported in the specification.

Support for claims 33-52 is not readily apparent in the specification. Applicants should point out the page and lines where the conditions and/or steps of each claim are recited or supported.

Claim Rejections - 35 USC § 112

Claims 20-29 and 32-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by failing to set forth clear, distinct and positive method steps that have a clear relationship to each other in providing a complete method. Claims 26-29 and 32 are additionally unclear by failing to set forth all steps needed for a complete method, and in claiming a methods not described in the specification.

In the last two lines of claims 20 and 25, the meaning and scope of conducting steps separately and in turn is uncertain. In what way are the steps conducted separately? The specification fails to define conducting steps separately as compared to not conducting steps separately. Similarly, in the last two lines of claims 26, 27 and 32,

the meaning and scope of preparing solutions separately and in turn is uncertain since the specification fails to define preparing solutions separately and in turn as compared to not preparing solutions separately and in turn.

5 For the meaning and scope of conducting steps and preparing solutions separately and in turn, applicants refer to page 9, lines 19-28. However, this disclosure relates to description of an apparatus and not to a description of a method as claimed.

10 The suggestion to cancel claims 26-29 and 32 was because these claims are not supported in the specification and are indefinite by not claiming a complete method. Applicants are not permitted to present claims of a scope not described and supported in the specification.

15 While amendments to the claims have removed some indefiniteness, indefiniteness still remains. Amendments were suggested in the previous office action of 7/8/02 to obviate the 112 rejections of claims 20, 25, 26-29 and 32.

20 In claims 33, 37, 41, 45 and 49, the meaning and scope of "nucleic acid-binding solid phase" is uncertain. Is this a phase that binds nucleic acid or a phase containing bound nucleic acid. Additionally, this recitation is inconsistent with requiring binding nucleic acid to a substance containing silicon oxide in the independent claims. A dependent claim may not broaden a claim on which it depends.

Claim Rejections - 35 USC § 103

25 Claims 20-29 and 32-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom et al (5,234,809) in view of Seligson et al

(4,935,342) for the type of reasons set forth in the previous office action of 7/8/02.

The claims are drawn to methods of recovering nucleic acids from a nucleic acid-bearing material by separate steps of releasing the nucleic acids from the material and forming an aqueous solution contain the released nucleic acid, adding a chaotropic agent to the aqueous solution, contacting the solution with a substance containing silicon dioxide to bind the nucleic acid to the substance, isolating the substance, washing the substance with a solution containing alcohol, eluting the nucleic, and removing alcohol for the eluted nucleic acid.

Boom et al disclose purifying nucleic acids from a nucleic acid-containing starting material by mixing the starting material, a chaotropic substance and a nucleic acid binding solid phase, separating the solid phase with nucleic acid bound thereto, washing the solid phase, and eluting nucleic acids from the solid phase. For example, see col 2, lines 13-22, and claims 1 and 12. The solid phase may be a silicon dioxide containing material (col 2, lines 52-60), and the chaotropic substance may be guanidine hydrochloride (col 3, line 63). Washing can be with a salt containing solution and an alcohol containing solution (col 4, lines 20-30). Nucleic acids contained by the nucleic acid-containing material may be released by cell lysis (col 2, lines 43-46).

Seligson et al disclose a method purifying nucleic acids by providing an aqueous solution containing nucleic acids as a sample, adsorbing nucleic acids to an ion exchange column from the sample, washing with a chloride salt solution and eluting the nucleic acids (see

claims). The salt may be sodium chloride (col 5, lines 60-65). To obtain the aqueous solution of nucleic acids that is applied to the column, nucleic acids are released from a starting material such as cells or viruses (col 8, lines 3-36) by contacting the cells or viruses with a lysing agent or detergent, and separating solids by centrifugation or filtration (col 8, lines 30-34) to obtain a supernatant that is an aqueous solution of nucleic acids in combination with water-soluble components of lysed cells or viruses.

When carrying out the nucleic acid purifying process of Boom et al, it would have been obvious to perform an initial step of releasing nucleic acids from cells or viruses to obtain an aqueous solution of nucleic acids for applying to the solid phase as suggested by Seligson et al since Boom et al disclose that starting material cells may be subjected to lysis (col 2, line 45), and since it would have been expected that nucleic acids bound within cells will unavailable for adsorbing to the solid phase of Boom et al. It would have been further obvious to add the chaotropic substance of Boom et al to the aqueous solution of nucleic acid resulting from cell lysis before adding the aqueous solution to the solid phase since Boom et al combines the chaotropic substance, starting material and solid phase together so released nucleic acids will immediately bind to the solid phase. When not desiring this advantage, it would have been clearly obvious to add the chaotropic substance to the starting aqueous nucleic acid solution in a separate step. In regard to using a chloride in a washing solution as in claim 23, it would have been obvious to add a chloride salt to the

washing of Boom et al to obtain the function of chloride salt for washing as disclosed by Seligson et al. Using potassium chloride or an acetate salt would have been a matter of obvious choice depending on individual preference and convenience since such salts are well known components of buffers, and the washing solution of Boom et al is a washing buffer (col 4, line 22). Acetate is a well known buffer component, and its use to produce the washing buffer would have been obvious. As to claims 33-52, the conditions of these claims would have been matters of obvious choice in view of the disclosures of the references.

Response to Arguments

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Applicants urges that releasing the nucleic acid, adding a chaotropic agent to a solution of the nucleic acid and then contacting the solution with a substance that binds nucleic acid in separate steps enhances recovery of the nucleic acid. However, this enhanced recovery is not supported by evidence. While Seligson et al may not be using a chaotropic salt and a solid phase including silica, this reference is purifying nucleic acids using a solid phase and eluting the nucleic acids. The use of a chaotropic salt and silica solid phase is taught by Boom et al. Boom et al and Seligson et al are sufficiently similar to be combinable. The references are combined together and must be considered together as a whole.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

25

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the
5 end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of
10 this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00
15 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number
20 (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651

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DMN
4/5/03